**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

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KIMBERLY GREMO,

Plaintiff,

v.

BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER HEALTHCARE PHARMACEUTICALS, INC., GE HEALTHCARE, INC., GENERAL ELECTRIC COMPANY, MALLINCKRODT, INC., MALLINCKRODT LLC, GUERBERT LLC, LIEBEL-FLARSHEIM COMPANY LLC, AMERISOURCE BERGEN CORPORATION, AMERISOURCE BERGEN DRUG CORPORATION,

Defendants.

1:19-cv-13432-NLH-AMD

**OPINION**

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**HILLMAN, District Judge**

This matter concerns FDA-approved gadolinium-based contrast agents ("GBCAs") administered intravenously by medical professionals to enhance the quality of magnetic resonance imaging ("MRI"). The MRIs are used to diagnose serious conditions, such as cancer, strokes and aneurysms. Plaintiff, Kimberly Gremo, claims that Defendants' GBCAs caused her "gadolinium toxicity, or Gadolinium Deposition Disease (GDD), as characterized by a multitude of symptoms," including "skin issues including rashes," "teeth issues including darkened teeth and spots," "brain fog and memory loss," and "loss of smell."

Plaintiff has filed suit against Defendants Bayer Corporation, Bayer HealthCare LLC, Bayer HealthCare Pharmaceuticals, Inc. (collectively "Bayer"), GE Healthcare, Inc., General Electric Company (collectively "GE"), Mallinckrodt, Inc., Mallinckrodt LLC (collectively "Mallinckrodt"), Guerbert LLC ("Guerbert"), Liebel-Flarsheim Company LLC ("Liebel-Flarsheim"), Amerisource Bergen Corporation, and Amerisource Bergen Drug Corporation (collectively "AmerisourceBergen"), as "manufacturers" or "sellers" of the GBCAs to which Plaintiff was exposed: Magnevist (manufactured and sold by Bayer), Omniscan (manufactured and sold by GE), and OptiMARK (manufactured and sold by Guerbet,

Mallinckrodt, Liebel-Flarsheim, and AmerisourceBergen[1]).

In her amended complaint,[2] Plaintiff has asserted two counts for Defendants' alleged violations of New Jersey's Product Liability Act (PLA), N.J.S.A. 2A:58C-2: failure to warn (Count I) and defective design (Count II). Plaintiff has also asserted a breach of express warranty claim against Defendants pursuant to N.J.S.A. 12A:2-313 (Count III).

Defendants have moved to dismiss all of Plaintiff's claims against them for numerous reasons. Plaintiff has opposed Defendants' motions. For the reasons expressed below, Defendants' motions will be denied.

## I. JURISDICTION

Defendants removed Plaintiff's complaint from state court to this Court pursuant to 28 U.S.C. § 1331.

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[1] According to Plaintiff's amended complaint, Defendant Mallinckrodt Inc. developed, invented, manufactured, tested, marketed, advertised, and sold a linear GBCA named OptiMARK before it sold its contrast media portfolio, including OptiMARK, to Guerbert LLC in 2015. Defendant Guerbert LLC manufactured, tested, marketed, advertised and sold OptiMARK before it removed OptiMARK from the United States market in 2018. In August 2016, OptiMARK's product label indicated that it was manufactured and distributed by Defendant Liebel-Flarsheim Company LLC. Defendant AmerisourceBergen has been engaged in the distribution, supply, marketing, and sale of OptiMARK in the State of New Jersey.

[2] Defendants moved to dismiss Plaintiff's original complaint. In response, Plaintiff filed an amended complaint. The motions to dismiss Plaintiff's original complaint are therefore moot. Pending are Defendants' motions to dismiss Plaintiff's amended complaint.

As the Court found in denying Plaintiff's motion to remand under the well-pleaded complaint rule (see Docket No. 108), even though the three counts in Plaintiff's complaint assert claims based on state law, on the face of Plaintiff's complaint, over which she is the "master," she has also raised claims arising under the laws of the United States, as well as claims that necessarily depend on resolution of a substantial question of federal law, to both of which § 1331 applies.[3] See Franchise Tax Bd. of Cal. v. Constr. Laborers Vacation Trust for S. Cal., 463 U.S. 1, 22, 28 (1983) ("[T]he party who brings the suit is master to decide what law he will rely upon," but "it is an independent corollary of the well-pleaded complaint rule that a plaintiff may not defeat removal by omitting to plead necessary

[3] For example, Plaintiff pleads: "Upon information and belief, the Defendants have or may have failed to comply with all federal standards and requirements applicable to the sale of GBCAs including, but not limited to, violations of various sections and subsections of the United States Code and the Code of Federal Regulations." (Pl. Compl., Docket No. 1 at 38, ¶ 126.) Plaintiff further claims that "notwithstanding the overwhelming evidence of causal association between GBCAs and NSF [renal impairment called nephrogenic systemic fibrosis], the FDA [Food and Drug Administration] and the GBCA industry have cast the issue of retention as separate from the medical community's experience with NSF, coming short of acknowledging any untoward health effects from gadolinium retention in non-renal patients," and "to date, the FDA and the GBCA industry have refused to acknowledge that GBCAs can cause NSF in renal patients but also can cause, in non-renal patients, a variety of NSF-like injuries and symptoms along a continuum, ranging from minor to severe." (Id. at 36, ¶¶ 120-21.)

federal questions in a complaint." "Congress has given the lower federal courts jurisdiction to hear, originally or by removal from a state court, only those cases in which a well-pleaded complaint establishes either that federal law creates the cause of action or that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal law.").[4] Thus, this Court may properly exercise subject matter jurisdiction over Plaintiff's complaint pursuant to 28 U.S.C. § 1331 and supplemental jurisdiction over Plaintiff's

[4] Separate from the well-pleaded complaint rule, another basis for federal jurisdiction is be complete pre-emption. See Ben. Nat'l Bank v. Anderson, 539 U.S. 1, 8 (2003) (explaining that there is an exception to the well-pleaded complaint rule "when a federal statute wholly displaces the state-law cause of action through complete pre-emption," and this exception exists because "[w]hen the federal statute completely pre-empts the state-law cause of action, a claim which comes within the scope of that cause of action, even if pleaded in terms of state law, is in reality based on federal law"). However, in contrast to complete pre-emption, the defenses of impossibility pre-emption and other pre-emption defenses may not serve as the basis for federal jurisdiction at the time of removal. See Caterpillar Inc. v. Williams, 482 U.S. 386, 393 (1987) (explaining that a case may not be removed to federal court on the basis of a federal defense, including the defense of pre-emption, even if the defense is anticipated in the plaintiff's complaint, and even if both parties concede that the federal defense is the only question truly at issue). Regardless of which type of pre-emption doctrine may possibly apply to Plaintiff's claims, as discussed below, the Court cannot determine at this stage in the case whether Plaintiff's PLA claims are pre-empted by federal law - either completely or through a pre-emption defense - and therefore federal pre-emption has not been established to support subject matter jurisdiction under that principle at this time.

other state law claims under 28 U.S.C. § 1367.[5]

## II. DISCUSSION

### A. Standard for Motion to Dismiss

When considering a motion to dismiss a complaint for failure to state a claim upon which relief can be granted pursuant to Federal Rule of Civil Procedure 12(b)(6), a court must accept all well-pleaded allegations in the complaint as true and view them in the light most favorable to the plaintiff. Evancho v. Fisher, 423 F.3d 347, 351 (3d Cir. 2005). It is well settled that a pleading is sufficient if it contains "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2).

"While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do . . . ." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007) (alteration in original) (citations omitted) (first citing Conley v. Gibson, 355 U.S. 41, 47 (1957); Sanjuan v. Am. Bd. of Psychiatry & Neurology, Inc.,

[5] Because there is no diversity of citizenship between Plaintiff and Defendants, subject matter jurisdiction under 28 U.S.C. § 1332(a) is unavailable.

40 F.3d 247, 251 (7th Cir. 1994); and then citing Papasan v. Allain, 478 U.S. 265, 286 (1986)).

To determine the sufficiency of a complaint, a court must take three steps: (1) the court must take note of the elements a plaintiff must plead to state a claim; (2) the court should identify allegations that, because they are no more than conclusions, are not entitled to the assumption of truth; and (3) when there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement for relief. Malleus v. George, 641 F.3d 560, 563 (3d Cir. 2011) (quoting Ashcroft v. Iqbal, 556 U.S. 662, 664, 675, 679 (2009) (alterations, quotations, and other citations omitted).

A district court, in weighing a motion to dismiss, asks "not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claim." Twombly, 550 U.S. at 563 n.8 (quoting Scheuer v. Rhoades, 416 U.S. 232, 236 (1974)); see also Iqbal, 556 U.S. at 684 ("Our decision in Twombly expounded the pleading standard for 'all civil actions' . . . ."); Fowler v. UPMC Shadyside, 578 F.3d 203, 210 (3d Cir. 2009) ("Iqbal . . . provides the final nail in the coffin for the 'no set of facts' standard that applied to federal complaints before Twombly."). "A motion to dismiss should be granted if the plaintiff is unable to plead 'enough

facts to state a claim to relief that is plausible on its face.'" Malleus, 641 F.3d at 563 (quoting Twombly, 550 U.S. at 570).

A court in reviewing a Rule 12(b)(6) motion must only consider the facts alleged in the pleadings, the documents attached thereto as exhibits, and matters of judicial notice. S. Cross Overseas Agencies, Inc. v. Kwong Shipping Grp. Ltd., 181 F.3d 410, 426 (3d Cir. 1999). A court may consider, however, "an undisputedly authentic document that a defendant attaches as an exhibit to a motion to dismiss if the plaintiff's claims are based on the document." Pension Benefit Guar. Corp. v. White Consol. Indus., Inc., 998 F.2d 1192, 1196 (3d Cir. 1993). If any other matters outside the pleadings are presented to the court, and the court does not exclude those matters, a Rule 12(b)(6) motion will be treated as a summary judgment motion pursuant to Rule 56. Fed. R. Civ. P. 12(b).

**B. Summary of Plaintiff's allegations**

Plaintiff's amended complaint contains almost 20 pages of explanatory background concerning the development of GBCAs, their effects on the human body, the interaction of the FDA with the GBCA industry for the approval, labeling, marketing, and sale of GBCAs, and Plaintiff's experience with Defendants' GBCAs. (Docket No. 62 at 12-31.) In Plaintiff's oppositions to Defendants' motions to dismiss, Plaintiff presents a two-page

summary of the information and allegations contained in her amended complaint:

> Gadolinium is a chemical element that does not occur naturally in the body and is toxic in its free, cationic state. *See* Amended Complaint, Doc. No. 62, at ¶¶ 90-92, 100. Because gadolinium is highly paramagnetic, it is particularly effective for use in Magnetic Resonance (MR) imaging, and gadolinium-based contrast agents (GBCAs) have been developed as means to introduce gadolinium into the body and enhance diagnostic imaging. *See id.* at ¶¶ 93-99. Because naturally occurring gadolinium is toxic, GBCAs are "chelated" constructs, meaning the gadolinium is bound in either a "linear" or "macrocyclic" compound. *See id.* at ¶¶ 101-110. Linear GBCAs are less stable and more prone to separation of the gadolinium from its compound (or "de-chelation"). *See id*. Once de-chelated, free gadolinium will bind to tissue or cells in a biological structure. *See id*. In other words, if the chelation separates or falls away from the gadolinium, the patient would become exposed to raw and highly toxic gadolinium. So chelation is designed to protect the human body from direct exposure to a toxic heavy metal. The kidneys play a central role in the clearance of GBCAs from the body, so predictably, patients with compromised kidney function are at risk for slower or reduced clearance of GBCAs, which in turn increases the risk of de-chelation and retention of free gadolinium in the body. *See id.* at ¶ 111. The undisputed public record shows that, in patients with compromised kidney function, GBCAs can cause the rare and often fatal disease, Nephrogenic Systemic Fibrosis (NSF), *see*, *e.g.*, *id.* at ¶¶ 112-116, and the class labeling for GBCAs has warned physicians about that risk since 2007. *See id.* at ¶¶ 115-116.
>
> Plaintiff Kimberly Gremo contends that NSF is the end-stage of a broader condition that runs on a continuum, with pre-cursor symptoms and ailments, such as those she has suffered, on one end and full-blown NSF on the other. *See*, *e.g.*, *id.* at ¶¶ 124, 147-48, 156-59. She contends that the risk for NSF and NSF-like injuries is not limited to those with compromised kidney function but instead extends to *all* patients exposed to GBCAs. *See id*. Furthermore, she contends that macrocyclic GBCAs, which have long been FDA-approved and available as alternatives to their linear counterparts in the United States, are more stable, less

> prone to de-chelation, and consequently safer alternatives. *See id.* at ¶¶ 105-110. Her suit alleges that Defendants knew or should have known about this safety information and yet failed to warn the medical community and failed to alter the design of their linear products to comport with that of their macrocyclics. *See id.* at ¶¶ 168-205.
>
> From 2007 to 2016, Plaintiff was exposed to the linear GBCAs manufactured by Defendants on at least ten separate occasions. *See id.* at ¶ 164. She was exposed to Mallinckrodt / Guerbet's OptiMARK on at least six occasions [; Bayer's Magnevist on at least one occasion; and GE's Omniscan on at least three occasions]. *See id.* She alleges that, as a direct and proximate result of her linear GBCA exposure, she developed gadolinium toxicity, evidenced by a multitude of symptoms, ailments, injuries and adverse health effects that she now suffers, to wit: skin issues, including rashes, dermatitis, burning, hyperpigmentation, rough patches, loss of elasticity, peeling and callus-like buildup; teeth issues, including darkened teeth and spots, cracking, and sensitivity; neurological issues, including brain fog and memory loss; pain in her hips, back, bones and joints; neuropathy; fatigue; muscle aches and fasciculation; and loss of smell. *See id.* at ¶¶ 165-67.

(See Docket No. 82 at 4-5; 83 at 5-6; 85 at 6-7.)

**C. Plaintiff's claims under the PLA**

Under the New Jersey Product Liability Act (PLA),

> A manufacturer or seller of a product shall be liable in a product liability action only if the claimant proves by a preponderance of the evidence that the product causing the harm was not reasonably fit, suitable or safe for its intended purpose because it: a. deviated from the design specifications, formulae, or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae, or b. failed to contain adequate warnings or instructions, or c. was designed in a defective manner.

N.J.S.A. 2A:58C-2.

The cited statutory text establishes three causes of action

under the PLA: (1) design defect, (2) manufacturing defect, or (3) warnings defect. Mendez v. Shah, 28 F. Supp. 3d 282, 296 (D.N.J. 2014) (citing Roberts v. Rich Foods, Inc., 139 N.J. 365, 375, 654 A.2d 1365 (N.J. 1995); Dziewiecki v. Bakula, 361 N.J. Super. 90, 97-98, 824 A.2d 241 (App. Div. 2003)). The standard of liability is that the product "was not reasonably fit, suitable or safe for its intended purpose." Id. (citing Cornett v. Johnson & Johnson, 414 N.J. Super. 365, 998 A.2d 543 (App. Div. 2010)). The "mere occurrence of an accident and the mere fact that someone was injured are not sufficient to demonstrate the existence of a defect." Id. (citation omitted).

Plaintiff has asserted a warnings defect claim and a design defect claim.

**1. Count I - Failure-to-Warn**

To prove a failure-to-warn claim, a plaintiff must show: (1) the product was defective; (2) the defect existed when the product left the defendant's control; and (3) the defect caused injury to a reasonably foreseeable user. Lopez v. Borough of Sayreville, 2008 WL 2663423, at *15–16 (N.J. Super. Ct. App. Div. 2008) (citing Coffman v. Keene Corp., 133 N.J. 581, 593, 628 A.2d 710 (1993)). In a failure-to-warn case, "the duty to warn is premised on the notion that a product is defective absent an adequate warning for foreseeable users that the product can potentially cause injury." Id. (citing Clark v.

Safety–Kleen Corp., 179 N.J. 318, 336, 845 A.2d 587 (2004)) (other citation omitted). The failure to provide necessary warnings constitutes a breach of duty. Id. (citation omitted).

Initially, the plaintiff must establish that the defendant had a duty to warn. Id. (citing James v. Bessemer Processing Co., 155 N.J. 279, 297–98, 714 A.2d 898 (1998)). The manufacturer of a product has a duty to warn about any risk relating to the product that it knows or ought to know, unless the risk and the way to avoid it are obvious. Id. (citing Feldman v. Lederle Labs., 97 N.J. 429, 434, 479 A.2d 374 (1984)) (other citation omitted). Once plaintiff establishes a duty to warn, she must then establish that an adequate warning was not provided. Id. (citation omitted). A manufacturer "shall not be liable for harm caused by a failure to warn if the product contains an adequate warning or instruction." N.J.S.A. 2A:58C-4.

An "adequate warning" is defined as:

> [O]ne that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to, the persons by whom the product is intended to be used....

N.J.S.A. 2A:58C-4.

"Causation is a fundamental requisite for establishing any product-liability action," and a "plaintiff must demonstrate . .

. the defect in the product was a proximate cause of the injury." Lopez, 2008 WL 2663423 at *15–16 (citation omitted). "Ordinarily, the jury considers issues of proximate cause." Id. (citing Shelcusky v. Garjulio, 172 N.J. 185, 206, 797 A.2d 138 (2002)).

In the context of products regulated by the FDA, such as GBCAs, issues of federal pre-emption arise. See Merck Sharp & Dohme Corp. v. Albrecht, 139 S. Ct. 1668, 1672 (U.S. 2019) (explaining that federal pre-emption "takes place when it is impossible for a private party to comply with both state and federal requirements") (quoting Mutual Pharmaceutical Co. v. Bartlett, 570 U. S. 472, 480 (2013) and citing U. S. Const., Art. VI, cl. 2). Applicable here, "[t]he state law that we consider is state common law or state statutes that require drug manufacturers to warn drug consumers of the risks associated with drugs. The federal law that we consider is the statutory and regulatory scheme through which the FDA regulates the information that appears on brand-name prescription drug labels. The alleged conflict between state and federal law in this case has to do with a drug that was manufactured by [Defendants] and was administered to [Plaintiff] without a warning of certain associated risks." Id.

"[S]tate law failure-to-warn claims are pre-empted by the Federal Food, Drug, and Cosmetic Act and related labeling

regulations when there is 'clear evidence' that the FDA would not have approved the warning that state law requires." Id. at 1676 (discussing Wyeth v. Levine, 555 U.S. 555, 571 (2009)). This "impossibility pre-emption" - i.e., federal law makes it impossible for a defendant to also comply with state law - is a "a demanding defense." Id. (discussing Wyeth, 555 U.S. at 573, 555, finding that "absent clear evidence that the FDA would not have approved a change to [the drug's] label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements"). Despite the FDA's oversight of drug labeling,[6] "a central premise of federal drug regulation [is] that the manufacturer bears responsibility for the content of its label at all times." Id. at 1677 (citing Wyeth, 555 U.S. at 570-71).

"[F]ederal law - the FDA's CBE ["changes being effected"]

[6] Prospective drug manufacturers work with the FDA to develop an appropriate label when they apply for FDA approval of a new drug. 21 U.S.C. §§ 355(a), 355(b), 355(d)(7); 21 C.F.R. § 314.125(b)(6). But FDA regulations also acknowledge that information about drug safety may change over time, and that new information may require changes to the drug label. Id. §§ 314.80(c), 314.81(b)(2)(i). Drug manufacturers generally seek advance permission from the FDA to make substantive changes to their drug labels. However, an FDA regulation called the "changes being effected" or "CBE" regulation permits drug manufacturers to change a label without prior FDA approval if the change is designed to "add or strengthen a ... warning" where there is "newly acquired information" about the "evidence of a causal association" between the drug and a risk of harm. 21 C.F.R. § 314.70(c)(6)(iii)(A).

regulation - permits drug manufacturers to change a label to reflect newly acquired information if the changes add or strengthen a . . . warning for which there is evidence of a causal association, without prior approval from the FDA." Merk, 139 S. Ct. at 1679 (quoting 21 C.F.R. § 314.70(c)(6)(iii)(A)) (quotations omitted). "Of course, the FDA reviews CBE submissions and can reject label changes even after the manufacturer has made them," and "manufacturers cannot propose a change that is not based on reasonable evidence." Id. (citing §§ 314.70(c)(6), (7). 314.70(c)(6)(iii)(A)). "But in the interim, the CBE regulation permits changes, so a drug manufacturer will not ordinarily be able to show that there is an actual conflict between state and federal law such that it was impossible to comply with both." Id.

Defendants in this case argue that the impossibility pre-emption doctrine requires the dismissal of Plaintiff's failure-to-warn claims under the New Jersey PLA.[7] At this pleading

[7] Several Defendants also argue that Plaintiff's claims against them fail to satisfy the pleading standards of Fed. R. Civ. P. 8 and Twombly/Iqbal, particularly because she often refers to "Defendants" collectively. Although it is often the case that pleading claims against defendants as a group without identifying who did what is fatal to the viability of those claims, see, e.g., Twombly, 550 U.S. at 558 (insisting "upon some specificity in pleading before allowing a potentially massive factual controversy to proceed" to an "inevitably costly and protracted discovery phase"), Plaintiff's amended complaint does not meet that fate. Plaintiff's amended complaint specifies which Defendant is responsible for which GBCA and when

stage, the Court disagrees.

As a primary matter, Plaintiff has properly pleaded her failure-to-warn claims under the PLA. Plaintiff alleges Defendants' GBCA product labels were defective (Amend. Compl. Docket No. 62 ¶¶ 170-174), the defect existed when the products left Defendants' control (id. ¶ 170), and the defect caused injury to Plaintiff, a reasonably foreseeable user (id. ¶¶ 181-182). Plaintiff has also pleaded how Defendants' failure to provide necessary warnings constitutes a breach of their duty to warn Plaintiff of the risks related to their GBCAs of which Defendants knew or should have known. (Id. ¶¶ 174-179.)

To determine whether Plaintiff's properly pleaded failure-to-warn claims are pre-empted by the Federal Food, Drug, and Cosmetic Act and related labeling regulations, Defendants must show by clear evidence that the FDA would not have approved the warning that Plaintiff contends state law requires. Merk, 139 S. Ct. at 1676 (citing Wyeth, 555 U.S. at 571). For Defendants

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Plaintiff was administered each GBCA. Because the product labeling (and thus allegations regarding Defendants' failure to warn of the risks of their GBCAs), the product design (and thus allegations concerning design defects), and the express warranties are all the same for each GBCA, Plaintiff's collective reference to "Defendants" is permissible, and indeed preferable, so that she avoids veering into Rule 12(f) territory if she were to restate every collective allegation specific to each Defendant. See Fed. R. Civ. P. 12(f) (providing that the court on its own or on the motion of defendant the court may strike redundant matter). Plaintiff's amended complaint does not run afoul of proper pleading standards.

to do this at the motion to dismiss stage, Defendants are constrained to point to the contents of Plaintiff's complaint, or "an undisputedly authentic document that a defendant attaches as an exhibit to a motion to dismiss if the plaintiff's claims are based on the document." Pension Benefit, 998 F.2d at 1196. Defendants, however, have not so constrained themselves.

Defendants assert various arguments for why the impossibility pre-emption doctrine bars Plaintiff's state law failure-to-warn claims, but as the Supreme Court has reiterated, impossibility pre-emption is "a demanding defense" rather than a pleading requirement. Moreover, the impossibility pre-emption defense places the burden on Defendants - and not Plaintiff - to support that defense with "clear evidence," which is evidence provided by Defendants that "shows the court that the drug manufacturer fully informed the FDA of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve a change to the drug's label to include that warning." Merk, 139 S. Ct. at 1672.

Even though "a judge, not the jury, must decide the pre-emption question," id. at 1676, that question is not properly before the Court to answer at this time. See, e.g., Wyeth, 555 U.S. at 572-73 (finding that after the completion of discovery and at the trial-ready stage of the case Wyeth's evidence for

its pre-emption defense failed for who reasons: (1) the record did not show that Wyeth supplied the FDA with an evaluation or analysis concerning the specific dangers that would have merited the warning, and (2) the record did not show that Wyeth attempted to give the kind of warning required by state law but was prohibited from doing so by the FDA) (quotations and alterations omitted).

Plaintiff's failure-to-warn claims against all Defendants[8]

[8] In addition to joining in on the arguments made by Mallinckrodt, AmerisourceBergen argues that it is entitled to dismissal of Plaintiff's product liability claims because it is a "product seller" within the meaning of N.J.S.A. 2A:58C-8 and it meets the requirements for immunity enumerated by N.J.S.A. 2A:58C-9. "While those in the wholesale and retail chain of distribution may potentially be liable for the foreseeable injuries proximately caused by defective products intended for ultimate sale to the public, they may be relieved from liability where they comply with the exculpatory provisions of the Products Liability Act, N.J.S.A. 2A:58C–9." D.J.L. v. Armour Pharmaceutical Co., 704 A.2d 104, 117 n.25 (N.J. Super. L. Div. 1997). To that end, AmerisourceBergen provides an affidavit to demonstrate the exculpatory provisions by "certifying the correct identity of the manufacturer of the product" at issue, demonstrate that it has not "exercised some significant control over the design, manufacture, packaging or labeling of the product relative to the alleged defect in the product which caused the injury," demonstrate that it neither "knew [nor] should have known of the defect in the product which caused the injury," and demonstrate that it did not "create the defect in the product that caused the injury." Because AmerisourceBergen has moved to dismiss Plaintiff's claims pursuant to Rule 12(b)(6), and AmerisourceBergen has not cited to any law that would permit this Court to consider its affidavit in the context of a Rule 12(b)(6) motion, the Court will deny AmerisourceBergen's motion. The Court additionally notes that AmerisourceBergen's status under the PLA does not affect Plaintiff's breach of express warranty claim against AmerisourceBergen, which claim is discussed below in Section II

in Count I may proceed.[9]

**2. Count II - Defective Design**

The elements for proving a design defect claim are essentially the same as for a failure-to-warn claim. Lopez v. Borough of Sayreville, 2008 WL 2663423, at *15–16 (N.J. Super. Ct. App. Div. 2008) (citing Jurado v. W. Gear Works, 131 N.J. 375, 385, 619 A.2d 1312 (1993)).

In determining whether a product was defectively designed, courts apply a risk-utility analysis. Lopez, 2008 WL 2663423, at *25 (citing Cavanaugh v. Skil Corp., 164 N.J. 1, 8, 751 A.2d 518 (2000); Lewis v. American Cyanamid Co., 715 A.2d 967, 980

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C. 3.

[9] Several Defendants also contend that the learned intermediary doctrine bars Plaintiff's failure-to-warn claims. The doctrine holds that the prescribing physician - as a learned intermediary - generally is in the best position to advise the patient of the benefits and risks of taking a particular drug to treat a medical condition. In re Accutane Litigation, 194 A.3d 503, 524 (N.J. 2018) (citation omitted). In the case of prescription drugs, the PLA codifies the learned intermediary doctrine, and a pharmaceutical manufacturer generally discharges its duty to warn the ultimate user of prescription drugs by supplying physicians with information about the drug's dangerous propensities. Id. (citing N.J.S.A. 2A:58C-2) (other citations omitted). Like Defendants' pre-emption defense, the resolution of whether the doctrine is applicable in this case, and if it is, whether it defeats Plaintiff's failure-to-warn claim, cannot be resolved through the instant motion to dismiss. See Hindermyer v. B. Braun Medical Inc., 2019 WL 5881073, at *11 n.4 (D.N.J. 2019) ("Determining whether a prescribing physician was given sufficient warning in connection with a defendant's medical product pursuant to the learned intermediary doctrine raises factual questions that generally cannot be resolved on an undeveloped record.").

(N.J. 1998)). "A plaintiff must prove either that the product's risks outweighed its utility or that the product could have been designed in an alternative manner so as to minimize or eliminate the risk of harm." Id. (citing Lewis, 715 A.2d at 980).

There are seven listed factors in the classical statement of the risk-utility analysis,[10] but the prevalent view is that

[10] The seven listed factors in the classical statement of the risk-utility analysis are:

> (1) The usefulness and desirability of the product—its utility to the user and to the public as a whole.
>
> (2) The safety aspects of the product—the likelihood that it will cause injury, and the probable seriousness of the injury.
>
> (3) The availability of a substitute product which would meet the same need and not be as unsafe.
>
> (4) The manufacturer's ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility.
>
> (5) The user's ability to avoid danger by the exercise of care in the use of the product.
>
> (6) The user's anticipated awareness of the dangers inherent in the product and their avoidability, because of general public knowledge of the obvious condition of the product, or of the existence of suitable warnings or instructions.
>
> (7) The feasibility, on the part of the manufacturer, of spreading the loss by setting the price of the product or carrying liability insurance. (Ordinarily, a consideration only for the court.)

Grier v. Cochran Western Corp., 705 A.2d 1262, 1269 n.4 (N.J. Super. Ct. App. Div. 1998).

unless one or more of the other factors might be relevant in a particular case, the issue upon which most claims will turn is the proof by plaintiff of a reasonable alternative design, the omission of which renders the product not reasonably safe. Cavanaugh v. Skil Corp., 751 A.2d 518, 522 (N.J. 2000) (citation omitted). The burden is on the plaintiff to prove "the existence of an alternative design that is both practical and feasible" and "safer" than that used by the manufacturer. Lopez, 2008 WL 2663423 at *25 (citing Lewis, 715 A.2d at 980) ("Plaintiffs who assert that the product could have been designed more safely must prove under a risk-utility analysis the existence of an alternative design that is both practical and feasible.").

Generally, the factfinder is required to perform a risk-utility analysis in order to determine whether a product is defective in its design, and in performing a risk-utility analysis, an expert opinion is ordinarily relied upon to establish a reasonable alternative design. Rocco v. New Jersey Transit Rail Operations, Inc., 749 A.2d 868, 879 (N.J. Super. Ct. App. Div. 2000). "Except in the rare case when the risk-utility analysis points to the appropriate result as a matter of law, the jury, not the court, ultimately resolves factual issues arising from a risk-utility analysis." Lewis, 715 A.2d at 979 (citing Dreier et al., *Current N.J. Products Liability and Toxic*

*Torts Law*, § 5.2 at 29 (1998)); see also Toms v. J.C. Penney Co., Inc., 304 F. App'x 121, 124 (3d Cir. 2008) (citations omitted) ("[T]he existence of a design defect is frequently proven through the testimony of an expert who has examined the product and offers an opinion on its design.").

Plaintiff alleges that the risks of Magnevist, Omniscan, and OptiMARK outweighed their utility, and Defendants could have and should have designed each product as a macrocyclic GBCA, which would have minimized or eliminated the risk of harm posed by Defendants' GBCAs. Plaintiff further claims that had Magnevist, Omniscan, and OptiMARK been designed without defect, Plaintiff's injuries would have been avoided. (Amend. Compl. Docket No. 62 ¶ 187-191, 193, 203.) Plaintiff has properly pleaded a viable design defect claim under the PLA.

Several Defendants argue, however, that Plaintiff's design defect claim is pre-empted by federal law, relying upon Mutual Pharmaceutical Co., Inc. v. Bartlett, 570 U.S. 472, 484 (2013). In Bartlett, the Supreme Court analyzed New Hampshire's product liability law and noted that New Hampshire employs the risk-utility analysis for design defect claims which requires the consideration of three factors: "the usefulness and desirability of the product to the public as a whole, whether the risk of danger could have been reduced without significantly affecting either the product's effectiveness or manufacturing cost, and

the presence and efficacy of a warning to avoid an unreasonable risk of harm from hidden dangers or from foreseeable uses." Bartlett, 580 U.S. at 483 (citation omitted). The Supreme Court observed that in "the drug context, either increasing the 'usefulness' of a product or reducing its 'risk of danger' would require redesigning the drug: A drug's usefulness and its risk of danger are both direct results of its chemical design and, most saliently, its active ingredients." Id. (citing 21 C.F.R. § 201.66(b)(2)). As the New Hampshire courts found, because the drug at issue in Bartlett was a generic drug, redesign was not possible for two reasons: (1) the FDCA requires a generic drug to have the same active ingredients, route of administration, dosage form, strength, and labeling as the brand-name drug on which it is based, and (2) the drug's simple composition rendered it chemically incapable of being redesigned. Id. at 483-84.

The only recourse for the plaintiff's state law design defect claim was to strengthen the drug's warning. Id. at 483. The Supreme Court held that this was in direct conflict with federal law because federal law prevents generic drug manufacturers from changing their labels: "When federal law forbids an action that state law requires, the state law is 'without effect.' Because it is impossible for Mutual and other similarly situated manufacturers to comply with both state and

federal law, New Hampshire's warning-based design-defect cause of action is pre-empted with respect to FDA-approved drugs sold in interstate commerce." Id. at 486-87 (citations omitted). Ultimately, the Supreme Court held "that state-law design-defect claims like New Hampshire's that place a duty on manufacturers to render a drug safer by either altering its composition or altering its labeling are in conflict with federal laws that prohibit manufacturers from unilaterally altering drug composition or labeling." Id. at 490.

To support its argument that Plaintiff's design defect claim is pre-empted by federal law, Defendants seize on the Bartlett Court's statement that a state law which requires a manufacturer to alter the drug's composition is in conflict with federal law. Defendants argue that Plaintiff's contention that they should stop selling their GBCA products altogether because they should have been designed as a macrocyclic instead of with a linear structure conflicts with federal law, which prohibits a drug manufacturer from changing the drug's composition once it has been approved by the FDA.

Bartlett did not announce such a cut-and-dry pre-emption rule. The Supreme Court stated, "[A]s we have tried to make clear, the duty to ensure that one's products are not 'unreasonably dangerous' imposed by New Hampshire's design-defect cause of action, involves a duty to make one of several

changes. In cases where it is impossible—in fact or by law—to alter a product's design (and thus to increase the product's 'usefulness' or decrease its 'risk of danger'), the duty to render a product 'reasonably safe' boils down to a duty to ensure 'the presence and efficacy of a warning to avoid an unreasonable risk of harm from hidden dangers or from foreseeable uses.'" Bartlett, 570 U.S. at 491-92. In this case, unlike the drug at issue in Bartlett, Plaintiff's design defect claim does not confer a duty on Defendants to design their GBCAs in a different way that would be impossible to achieve. Plaintiff claims that a safer design of a linear GBCA is a macrocyclic structure, such as ProHance, Gadovist, and Dotarem, which "pose a lower risk of transmetallation compared to linear GBCAs because of stronger binding and chemical stability under physiologic conditions." (Amend. Compl. Docket No. 62 ¶ 193.)

Simply because Plaintiff claims that Defendants should redesign their GBCAs to make them safer does not mean that Plaintiff is demanding that Defendants cease making their GBCAs at all. By way of example, where a refrigerator leaks water and a plaintiff claims a design defect is the culprit, the plaintiff's claim that a better design would fix the problem necessarily requires a change to the composition of the refrigerator such that the manufacturer, if it implemented such

design change, would no longer sell its original product. In that sense, the refrigerator manufacturer would have ceased selling its originally designed refrigerators altogether. If Defendants' interpretation of Bartlett were to stand, then all design defect claims would be rendered impossible and therefore not actionable because any alteration of a product's design changes its original structure, and technically results in a manufacturer no longer making that original product.

In Bartlett, it was impossible for the drug manufacturer to redesign the drug's composition because it was a generic drug required to identically match the brand drug. Here, Plaintiff has claimed that a safer redesign of Defendants' GBCAs is possible. Accepting that premise as true as it must, the Court cannot find at the motion to dismiss stage that Plaintiff's design defect claims are pre-empted by federal law.

**3. Count III - breach of express warranty**

To state a claim for breach of express warranty under New Jersey law,[11] a plaintiff must allege the following three

[11] Under the New Jersey U.C.C., N.J.S.A. 12A:2-313, an "express warranty" is:

> (1) Express warranties by the seller are created as follows:
>
> (a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.

elements: "(1) that Defendant made an affirmation, promise or description about the product; (2) that this affirmation, promise or description became part of the basis of the bargain for the product; and (3) that the product ultimately did not conform to the affirmation, promise or description." Snyder v. Farnam Companies, Inc., 792 F. Supp. 2d 712, 721 (D.N.J. 2011).

"A statement can amount to a warranty, even if unintended to be such by the seller, if it could fairly be understood ... to constitute an affirmation or representation that the [product] possesse[s] a certain quality or capacity relating to future performance." Volin v. General Electric Company, 189 F. Supp. 3d 411, 420 (D.N.J. 2016) (citations omitted). "[S]tatements that are nothing more than mere puffery are not considered specific enough to create an express warranty." Snyder, 792 F. Supp. 2d at 721.

"Under New Jersey law, a representation is presumed to be part of the basis of the bargain 'once the buyer has become

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> (b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.
>
> (c) Any sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model.

N.J.S.A. 12A:2-313.

aware of the affirmation of fact or promise' and can be rebutted by 'clear affirmative proof that the buyer knew that the affirmation of fact or promise was untrue.'" Volin, 189 F. Supp. 3d at 420 (citing Viking Yacht Co. v. Composites One LLC, 496 F. Supp. 2d 462, 469 (D.N.J. 2007) (quoting Liberty Lincoln–Mercury, Inc. v. Ford Motor Co., 171 F.3d 818, 825 (3d Cir. 1999) (internal quotation omitted)).

Plaintiff claims that the product labeling for Magnevist, Omniscan, and OptiMARK was identical in all material respects, and that they represented: a. Linear GBCAs are generally safe for use; b. Linear GBCAs are not any less safe or stable than macrocyclic GBCAs; c. GBCAs pose a risk of NSF only to patients with kidney conditions; d. GBCAs are contraindicated only in patients with chronic, severe kidney disease, acute kidney injury, or a history of severe hypersensitivity; and e. Any retention of gadolinium in non-kidney patients is harmless. (Amend. Compl. Docket No. 62 ¶ 209.) Plaintiff further claims that "Defendants breached said express warranties by delivering to Plaintiff and her prescribing physicians linear GBCAs that did not confirm to and/or meet those warranties," and "[e]ach of Defendant's breach of the aforesaid express warranties was direct and proximate cause of Plaintiff's injuries and damages as set forth herein." (Id. ¶¶ 210-11.) Plaintiff has properly pleaded her breach of express warranty

claims against Defendants.[12]

**4. Punitive Damages**

Defendants argue that Plaintiff's request for punitive damages must be stricken because New Jersey's PLA prohibits the award of punitive damages for FDA-approved drugs, and such an award of punitive damages is otherwise pre-empted by federal law. Plaintiff argues that her claim for punitive damages may proceed to discovery because such a claim is not pre-empted, and she is entitled to offer proof of Defendants' misrepresentations to the FDA to support punitive damages for her failure-to-warn and design defect claims. The PLA provides:

> Punitive damages shall not be awarded if a drug or device or food or food additive which caused the claimant's harm was subject to premarket approval or licensure by the federal Food and Drug Administration under the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040, 21 U.S.C. § 301 et seq. or the "Public Health Service Act," 58 Stat. 682, 42 U.S.C. § 201 et seq. and was approved or licensed; or is generally recognized as safe and effective pursuant to conditions established by the federal Food and Drug Administration and applicable regulations, including

[12] Several Defendants argue that Plaintiff's breach of express warranty claims against them are barred because she did not provide them with reasonable pre-suit notice of those claims. The Court will not dismiss Plaintiff's breach of express warranty claims on this basis. See Devane v. Church & Dwight Co., Inc., 2020 WL 998946, at *7 (D.N.J. 2020) (citing Taylor v. JVC Americas Corp., 2008 WL 2242451, at *6 (D.N.J. 2008) (quoting Strzakowlski v. General Motors Corp., 2005 WL 2001912, *3 (D.N.J. 2005) ("[E]ven if notice to [Defendant] is necessary under section 2–607(3)(a), the filing of Plaintiff's Complaint satisfied this requirement," and "whether this notice-by-suit was provided within a reasonable time is a question for the fact finder. Therefore, the timing question is beyond the scope of a motion to dismiss for failure to state a claim.")).

> packaging and labeling regulations. However, where the product manufacturer knowingly withheld or misrepresented information required to be submitted under the agency's regulations, which information was material and relevant to the harm in question, punitive damages may be awarded.

N.J.S.A. 2A:58C-5(c).

To support their pre-emption argument, Defendants rely upon a New Jersey Appellate Division case, McDarby v. Merck & Co., Inc., 949 A.2d 223, 275 (N.J. Super. Ct. App. Div. 2008), which in turn relies upon a United States Supreme Court case, Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341, 347 (2001). In Buckman, the plaintiffs alleged that a drug manufacturer made fraudulent representations to the FDA as to the intended use of defendant's bone screws and that, as a result, the devices were improperly given market clearance and were subsequently used to the plaintiffs' detriment. Buckman, 531 U.S. at 347. The Supreme Court held that the plaintiffs' state-law fraud-on-the-FDA claims conflicted with, and were impliedly pre-empted by, federal law. Id. at 348. The Supreme Court explained, "The conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives. The balance sought by the Administration can be skewed by allowing fraud-on-the-FDA claims under state tort law." Id.

In McDarby, the New Jersey Appellate Division noted that the punitive damages provision of New Jersey's PLA was "designed to effectuate the State's interest in punishing unlawful conduct," and "[i]n that context, a plaintiff bringing a product liability action acts in a fashion akin to a private attorney general, since any damages awarded on his punitive damage claim do not compensate him for his injury, but instead vindicate societal interests. And in this context, the statutory focus, like that in Buckman, is narrowly drawn upon a defendant's act of knowingly withholding from or misrepresenting to the FDA information material to the harm alleged. This limited claim for punitive damages [] focused upon deterring a manufacturer's knowingly inadequate response to FDA informational requirements . . . ." McDarby, 949 A.2d at 275 (citations omitted).

The McDarby court concluded, "Because the punitive damages provisions of N.J.S.A. 2A:58C–5c impinge upon federal statute and regulation to the same extent that was recognized in Buckman, 531 U.S. at 349, we find the principles of implied pre-emption applied by the Court in Buckman to be applicable here." Id. at 276. Thus, the McDarby court reversed the trial court's award of punitive damages on the plaintiff's claim that if Merk had furnished the FDA with the complete meta-analysis, the FDA would have responded in a different fashion to Merck's supplemental new drug application. Id.

Defendants argue that Plaintiff's claim for punitive damages based on Defendants' alleged misrepresentations to the FDA are pre-empted under McDarby and Buckman. Plaintiff counters that Buckman does not stand for the proposition that Plaintiff is prohibited from offering proof of, as opposed to asserting a claim regarding, a drug company's misrepresentations to the FDA to support her state law failure-to-warn and design defect claims.

Although it appears to this Court that the holding in McDarby effectively invalidated the fraud-on-the-FDA punitive damages provision of N.J.S.A. 2A:58C-5(c) by finding it is pre-empted by federal law, the New Jersey Supreme Court did not explicitly consider that finding, instead finding that its grant of certification on the issue was improvidently granted based on the United States Supreme Court's decision in Wyeth. See McDarby v. Merck & Co., Inc., 979 A.2d 766 (N.J. 2009) ("This matter having been duly considered and the Court having determined that in light of the decision of the United States Supreme Court in Wyeth v. Levine, --- U.S. ----, 129 S. Ct. 1187, 173 L. Ed. 2d 51 (2009), certification was improvidently granted.").

The United States Supreme Court in Wyeth stated, "If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption

provision at some point during the FDCA's 70–year history." Wyeth, 555 U.S. 555 at 574. The Supreme Court further explained,

> In keeping with Congress' decision not to pre-empt common-law tort suits, it appears that the FDA traditionally regarded state law as a complementary form of drug regulation. The FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge. State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information. Failure-to-warn actions, in particular, lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times. Thus, the FDA long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation.

Id. at 578-79.

Keeping in mind these consideration of the Supreme Court regarding the permissible co-existence of FDA regulations and state court tort law, this Court declines to hold at this stage in the case that Plaintiff's request for punitive damages under New Jersey's PLA is pre-empted by federal law. For the same reasons as the Court's analysis of the impossibility pre-emption doctrine regarding Plaintiff's failure-to-warn claims, the Court will not strike Plaintiff's request for punitive damages at this time.

**5. Statute of limitations**

Several Defendants argue that Plaintiff's claims are barred

by the two-year statute of limitations because Plaintiff filed her complaint on April 24, 2019, but her claims accrued in January 2015. Defendants contend that a "GoFundMe" page set up by Plaintiff's husband on January 26, 2015, which requested financial assistance for Plaintiff's chelation therapy, shows that Plaintiff was aware of her alleged injuries due to Defendants' GBCAs at that time, which is well outside the two-year statute of limitations.

Plaintiff raises several arguments in opposition. The Court agrees with all of them: (1) Plaintiff pleads in her amended complaint, which the Court accepts as true, that she "was reasonably unaware, and had no reasonable way of knowing, that Plaintiff's injuries described herein were caused by Defendants' conduct until at the very earliest, Summer 2018" (Amend. Compl. Docket No. 62 at 39-40 "TOLLING: FRAUDULENT CONCEALMENT, DISCOVERY RULE, AND EQUITABLE ESTOPPEL"); (2) at the motion to dismiss stage, the application of the statute of limitations must be apparent on the face of complaint,[13] and that

[13] See Stephens v. Clash, 796 F.3d 281, 288 (3d Cir. 2015) (citations and quotations omitted) ("A statute of limitations defense is an affirmative defense that a defendant must usually plead in his answer. Nevertheless, we permit a limitations defense to be raised by a motion under Rule 12(b)(6) only if the time alleged in the statement of a claim shows that the cause of action has not been brought within the statute of limitations. Thus, a district court may grant a motion under Rule 12(b)(6) raising a limitations defense if the face of the complaint demonstrates that the plaintiff's claims are untimely. But

is not the case here; and (3) Plaintiff's husband's awareness of Plaintiff's sickness and the request to friends and family for financial assistance with various treatments does not plainly translate into Plaintiff's awareness that Defendants' alleged violations of the PLA and their express warranties caused her injuries.

The Court will not dismiss Plaintiff's claims based on Defendants' statute of limitations defense.

## III. CONCLUSION

For the foregoing reasons, Defendants' motions to dismiss Plaintiff's claims pursuant to federal pre-emption doctrines will be denied without prejudice. Plaintiff's counts under the New Jersey PLA and for breach of express warranty, as well as her request for punitive damages, may proceed to discovery.

An appropriate Order will be entered.

Date: June 29, 2020
At Camden, New Jersey

s/ Noel L. Hillman
NOEL L. HILLMAN, U.S.D.J.

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federal courts may not allocate the burden of invoking the discovery rule in a way that is inconsistent with the rule that a plaintiff is not required to plead, in a complaint, facts sufficient to overcome an affirmative defense. Thus, if the pleading does not reveal when the limitations period began to run, then the statute of limitations cannot justify Rule 12 dismissal.").